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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,325	05/24/2001	Bryan Sykes	620-137	6806

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EXAMINER

SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/806,325	<b>Applicant(s)</b> SYKES ET AL.	
	<b>Examiner</b> Monika B Sheinberg	<b>Art Unit</b> 1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i>        |

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**DETAILED ACTION**

**Election/Restrictions**

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, drawn to a method of identifying individuals susceptible to osteoarthritis as directed by alleles of D11S937.

Group II, claim(s) 4-10, drawn to a method of genetic loci isolation as directed by alleles of D11S937.

Group III, claim(s) 11 drawn to a method of determining susceptibility to osteoarthritis by identification of sibling allele sharing as directed polymorphic markers. *(If this group is elected, please see marker restriction requirement further below).*

Group IV, claim(s) 12, drawn to a method of identifying individuals susceptible to osteoarthritis directed by analysis of genomic regions one or more of the following specific markers: D11S901, D11S903, and D11S907.

Group V, claim(s) 13, drawn to a method of identifying individuals susceptible to osteoarthritis directed by analysis of genomic regions with a specified polymorphic marker located within 20cM of D11S937.

Group VI, claim(s) 14 and 15, drawn to a method of identifying individuals susceptible to osteoarthritis directed by analysis of genomic regions with one or more of the following specific markers: D6S273 and DXS1068.

Group VII, claim(s) 16 and 18, drawn to a method of loci identification as directed by the genomic screening of specific polymorphic markers in the region between polymorphic markers D11S358 and D11S35. *(If this group is elected, please see marker restriction requirement further below).*

- Please note that claim 17 is an incomplete claim.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

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technical features for the following reasons: The special technical feature of Groups I and IV-VI are the identification of individuals susceptible to osteoarthritis due to the presence of a particular allele or allele combinations; the special technical feature of Groups II is the isolation of specified loci; the special technical feature of Group III is the determination of a score of susceptibility through sibling allele sharing; and the special technical feature of Group VII is the identification of loci by genomic screening. Due to the method practiced differing in the goals of the method steps particular to alleles, Groups such as I and IV are unrelated because Group I is directed to allele D11S937 and Group IV is directed to alleles D11S901, D11S903, and D11S907. Each particular allele in itself requires different means for analysis due to different genomic region locations and functions. Therefore Groups I-VII have different special technical features. In addition, the body of the claims does not accomplish the goals of the preambles set forth of the method/process claims. Thus a method, as seen for example in Group III, is interpreted as loci/marker analysis method of the recited loci. As such, the method of Group III lacks novelty due to anticipation by the method demonstrated by Laass *et al.* (*Hum. Genet.*, 1997). Laas *et al.* demonstrates a method of linkage analysis (Table 1, p. 379; and Figure 3, p. 380) by haplotyping the specified loci of clinical samples as described in claim 11.

#### **Marker Restriction Requirement**

In addition, Group III and VII detailed above, directed to different polymorphic markers, reads on patentably distinct genomic regions for analysis. These markers are deemed to lack unity of invention because they are patentably distinct.

The markers are as follows:

#### ***(Claims 11 and 16)***

D2S202	D3S1266	D4S231	D4S415
D6S260	D6S273	D6S286	D6S281
D7S669	D7S530	D11S907	D11S903
D11S901	D17S807	D17S789	DXS1068

Applicant is required, in reply to this action, to elect a single marker from claim 11 or claim 16 to which the claims shall be restricted. Each individual polymorphic marker defines a specific genomic region in which different goals and methods steps are required for analysis.

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The results of an analysis of allele D4S231 will not predict the results of an analysis of a different allele such as D11S901. Examination will be restricted to only the elected polymorphic marker.

### Conclusion

A telephone call was made to B.J. Sadhoff on 25 August 2003 to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Jehanne Souaya, can be reached at 703-308-6565. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

August 25, 2003  
Monika B. Sheinberg  
Art Unit 1634

*MBS*

JEHANNE SOUAYA  
PATENT EXAMINER

*Jehanne Souaya*  
*August 25, 2003*